SEP 17 2003

Akers Laboratories, Inc.
Blood Cell Separator
510(k) Notification

PREMARKET NOTIFICATION
510(k) Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92"

"The assigned 510(k) number is: K030815 "

807.92 (a)(1):

Name:	Akers Laboratories, Inc.
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Phone:	(856) 848-8698
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Contact:	Barbara A. Bagby

807.92 (a)(2): Device Name – trade name and common name, and classification

Trade name:	Blood Cell Separator
Common name:	Blood Cell/Plasma Separator
Classification:	21 CFR 862.1675 Product Code: JKA

807.92 (a)(3): Identification of the legally marketed predicate device

"Akers Laboratories, Inc. Blood Cell Separator is substantially equivalent to the Vacutainer® Brand Tube for the Determinations Requiring Serum and the Vacutainer® Brand Tube for Hematology and Selective Chemistry Determination, both manufactured and distributed by Becton, Dickinson Company for use in preparing a sample for lithium colorimetric diagnostic testing. Both are pre-amendment devices."

807.92 (a)(4): Device Description

The Blood Cell Separator is intended for use as a sample preparation aid in *in vitro* lithium colorimetric diagnostic testing systems where a precise, micro-volume sample of serum or plasma is required to be collected from a whole blood specimen.

The Blood Cell Separator consists of two components packaged in a single separator device: the membrane system and a capillary tube. The device is based upon a multiple layer membrane system designed to separate blood cells and serum/plasma. This is achieved through the attraction and capture of blood cells from a whole blood specimen applied to the surface of the membrane system. The residual liquid continues to flow laterally to the tip of the membrane at which time the capillary tube fills vertically to the pipette's fixed, controlled volume and is ready to use.

807.92 (a)(5): Intended Use

The Blood Cell Separator is intended for the use as a sample preparation aid to *in vitro* Lithium colorimetric diagnostic testing systems where a precise, micro-volume sample of serum or plasma is required to be collected from a whole blood specimen. The liquid produced by the device is dependent upon the sample collected; whole blood collected with an anti-coagulant will produce plasma, and whole blood collected without an anti-coagulant will produce serum.

807.92 (a)(6): Technological Similarities and Differences to Predicate

The following chart exhibits similarities and differences between the Akers Laboratories, Inc. Blood Cell Separator is substantially equivalent to the Vacutainer® Brand Tube for the Determinations Requiring Serum and the Vacutainer® Brand Tube for Hematology and Selective Chemistry Determination, both manufactured and distributed by Becton, Dickinson Company for use in preparing a sample for lithium colorimetric diagnostic testing. Both are pre-amendment devices.

Characteristic	**AKERS Blood Cell Separator**	**PREDICATE DEVICE** BD Vacutainer® Brand Tube for the Determinations Requiring Serum	**PREDICATE DEVICE** BD Vacutainer® Brand Tube for Hematology and Selective Chemistry Determinations
510(k) Number	---------	Pre-amendment	Pre-amendment
Used to collect and separate blood specimens	Yes	Yes	Yes
Separates cells directly from whole blood sample	Yes	Yes	Yes
Produces a liquid fraction	Yes	Yes	Yes
Requires centrifugation technique to separate cells (pre-treatment)	No	Yes	Yes
Separation achieved with human intervention	No	Yes	Yes
Contains an anticoagulant	No	No	Yes
Lectin coated membrane system	Yes	No	No
Separated fluid passes through filter medium	Yes	No	No
Yields precise micro-volume sample	Yes	No	No
Sample produced used in lithium colorimetric analysis	Yes	Yes	Yes
Description of Principle	Based upon the natural clotting process of whole blood and the subsequent separation of cellular components from serum or plasma by filtration.	Based upon the natural clotting process of whole blood and the subsequent separation of cellular components from serum or plasma by centrifugation.	Based upon the natural clotting process of whole blood and the subsequent separation of cellular components from serum or plasma by centrifugation.

The differences in the devices do not raise new issues of safety and effectiveness.

807.92 (b)(1): Brief Description of Non-clinical data

Studies were performed to evaluate the analytical performance of the Blood Cell Separator as an aid in preparing a sample for lithium colorimetric diagnostic testing analysis.

The precision standard deviation (SD) ranged from 0.04 to 0.11 mEq/L when samples were assayed in multiple runs over multiple days for both EDTA plasma and serum. Using serum, the percent coefficient of variation (%CV) of a control at ~ 1.5 mEq/L lithum was 6.4% when tested in 50 runs over five days (10 runs per day). Using EDTA plasma, the percent coefficient of variation (%CV) of a control at ~ 0.8 mEq/L lithum was 6.7% when tested in 30 runs over three days (10 runs per day).

The Blood Cell Separator was compared to a routine cell separating technique. Results were listed as total cells per High Powered Field (HPF). The summary data reflected that either method provides a liquid sample containing no blood cells.

The assay sensitivity was 0.03 mEq/L with BD Vacutainer Tube EDTA Plasma Separation and 0.03 mEq/L using the Akers Blood Cell Separation method illustrating equivalent performance.

The daily standard deviation obtained during the five (5) day precision study for the blood cell separator ranged from 0.01 mEq/L to 0.04 mEq/L for the low value sample and 0.03mEq/L to 0.07 mEq/L for the high value sample compared to daily standard deviations for the BD vacutainer system of 0.03 mEq/L to 0.08 mEq/L and 0.03 mEq/L to 0.08 mEq/L respectively for the low and high value samples. The composite percent coefficient of variation (%CV) for the blood cell separator system based on 50 samples over 5 days was 8.4% for the low value sample and 5.7% for the high value sample compared to 9.5% and 6.1%, respectively for the BD vacutainer system. These results illustrated a highly favorable precision performance of the blood cell separator system when compared to the BD vacutainer system.

The recovery correlation yielded an R value of 0.993 and an R^2 value of 0.9866 illustrating very tight correlation between the two pathways.

807.92 (b)(2): Brief Description of Clinical Data

Not applicable, all testing performed via bench by independent laboratory and/or internally.

807.92 (b)(3): Conclusions from Non-clinical and Clinical Testing

The Blood Cell Separator was evaluated for performance characteristics in comprehensive studies. These studies demonstrated that the test is safe and effective for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 2003

Akers Laboratories, Inc.
c/o Mr. Heinz-Joerg Steneberg
TUV Rheinland of North America
12 Commerce Road
Newtown, CT 06470

Re: k030815
Trade/Device Name: Blood Cell Separator
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: August 29, 2003
Received: September 2, 2003

Dear Mr. Steneberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Akers Laboratories, Inc.
Blood Cell Separator
510(k) Notification

510(k) Number (if Known): K030815 **Not known at this time**

Device Name: Blood Cell Separator

Indications for Use:

The Blood Cell Separator is intended for the use as a sample preparation aid to *in vitro* Lithium colorimetric diagnostic testing systems where a precise, micro-volume sample of serum or plasma is required to be collected from a whole blood specimen. The liquid produced by the device is dependent upon the sample collected; whole blood collected with an anti-coagulant will produce plasma, and whole blood collected without an anti-coagulant will produce serum.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CRF 801.109) OR Over-the-Counter Use _____ (Optional Format 1-2-96)

Jean Cooper
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030815